K082231 1/1

6 510(k) Summary JAN 12 2009

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, #100
Austin, TX 78754-3832

510(k) CONTACT: Debbie Stearns
Phone: (512) 836-5001 x1548

TRADE NAME: Ascension® Silicone PIP

COMMON NAME: Prosthesis, finger, constrained, polymer

CLASSIFICATION: 21 CFR 888.3230

PRODUCT CODE: KYJ

PANEL: Orthopedic

PREDICATE DEVICES:
K022892 – Ascension Silicone MCP
K001922 – DePuy Neuflex PIP Finger

DEVICE DESCRIPTION:
The Ascension® Silicone PIP is a single component silicone spacer consisting of a proximal and distal intramedullary stem and a central flexible hinge. The central flexible hinge has a pre-flexed angle of 15 degrees. The Ascension Silicone PIP is available in 6 sizes for use in left or right applications. Device components are provided sterile in individual packaging.

INTENDED USE:
The indications for use of the Ascensions Silicone PIP are for replacement of the proximal interphalangeal joint in patients with advanced osteoarthritis, post-traumatic arthritis and rheumatoid arthritis.

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of the Ascension Silicone PIP and the DePuy NeuFlex PIP Finger Implant (K001922) and Ascension Silicone MCP (K022892) show similar material, design features, surgical technique and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascension Orthopedics, Inc.
% Ms. Debbie Stearns
8700 Cameron Road, Suite 100
Austin, Texas 78754-3832

JAN 12 2009

Re: K082231
Trade/Device Name: Ascension Silicone PIP
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: II
Product Code: KYJ
Dated: December 23, 2008
Received: December 29, 2008

Dear Ms. Stearns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

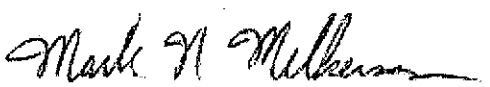
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(K) Number: K082231

Device Name: Ascension® Silicone PIP

Indications for Use:

The indications for use of the Ascension Silicone PIP are for cementless replacement of the proximal interphalangeal joint in patients with advanced osteoarthritis, post-traumatic arthritis and rheumatoid arthritis.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Part 21 CFR 801Subpart B) (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082231